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New Serum Biomarkers for Prostate Cancer Diagnosis

Ref# RP12-013

Keywords: Castration resistant prostate cancer, Interleuken-8, Tumor Necrosis Factor α, serum biomarker, prostate

specific antigen (PSA).

<u>Collaboration Research Opportunity:</u> Roswell Park Cancer Institute is seeking research partners to help co-develop The use of IL-8, TNF- α , and sTNFR1 as possible biomarkers for the early detection and surveillance of prostate cancer.

<u>Summary:</u> At present, no commercially available biomarkers have been identified to differentiate between men with and without prostate cancer (CaP), or to differentiate high risk CaP from indolent CaP better than the PSA test. The widespread use of PSA testing has resulted in 1.3 million additional men diagnosed and 1.0 million men treated for CaP unnecessarily. In addition, the PSA test has been reported to be of limited value in differentiating benign prostatic disease from CaP and this has resulted in 700,000 unnecessary prostate biopsies annually in the U.S.

<u>Technology:</u> Progression of CaP is accompanied by modulation of several key regulatory molecules, including vascular endothelial growth factor, interleukin-8 (IL-8), basic fibroblast growth factor (FGF), tumor necrosis factor- α , and IGF-1 and their receptors. These changes may take the form of up or down-regulation of growth factors or their receptors as well as changes in paracrine or autocrine mediation of growth. Scientists at Roswell Park Cancer Institute have done a pilot study involving concurrent serum measurements of IL-8, TNF- α , and sTNFR1 in normal healthy individuals (controls), men with elevated PSA with a negative prostate biopsy (e1PSA_negBx), patients diagnosed with localized CaP, and patients with castrate resistant prostate cancer (CRPC).

Potential Commercial Applications:

- Early stage prostate cancer diagnostic to help address shortcomings of PSA test alone.
- Late stage prognostic in that TNF- α alone or in combination with PSA significantly distinguished men with CRPC from those with localized CaP, compared with PSA test alone.
- Utility of serum biomarkers for early detection or for treatment decision making, as well as a monitoring tool.

Competitive Advantages:

- \triangleright The specificity and sensitivity of a PSA-based CaP diagnosis can be significantly enhanced by concurrent serum measurements of IL-8, TNF-α, and sTNFR1.
- \triangleright sTNFR1 and TNF- α independently and sTNFR1 and IL-8 in combination are highly significantly predictive in differentiating men with CaP from those without, compared with PSA alone.
- \triangleright TNF- α alone or in combination with PSA significantly distinguished men with CRPC from those with localized CaP, compared with PSA test alone.

Development Status: Provisional Patent Pending

Inventor: Dr. Kailash Chadha, PhD and Dr. Willie Underwood

Additional References: Clinical Cancer Investigation Journal, New Serum Biomarkers for Prostate Cancer Diagnosis, Vol.

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